

HFA 305

SEP 17 2001

DATE OF APPROVAL LETTER: \_\_\_\_\_

## FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-144

TETROXY<sup>®</sup> HCA (oxytetracycline HCl)

“change of withdrawal period for turkeys and swine to zero days”

Sponsored by Bimeda, Inc.

ANADA 200-144

F05-1

**I. GENERAL INFORMATION:**

**ANADA:** 200-144

**Sponsor:** Bimeda, Inc.  
288 County Road 28  
Le Sueur, MN 56058

**Generic Name:** Oxytetracycline HCl

**Trade Name:** TETROXY<sup>®</sup> HCA SOLUBLE POWDER

**Marketing Status:** OTC

**Effect of the Supplement:** Change of withdrawal period for turkeys and swine to zero days

**II. INDICATIONS AND DOSAGES FOR USE:**

Turkeys: 200 to 400 mg per gallon for control of hexamitiasis caused by *Hexamita meleagridis*, susceptible to oxytetracycline.  
400 mg per gallon for control of infectious synovitis caused by *Mycoplasma synoviae*, susceptible to oxytetracycline.  
25-mg/lb body weight in GROWING TURKEYS for control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline.

Swine: 10 mg/lb body weight FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE – Bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona*, susceptible to oxytetracycline.

### **III. DRUG EFFECTIVENES AND TARGET ANIMAL SAFETY:**

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 10, 2000).

Based upon the formulation characteristics of the generic product, TETROXY<sup>®</sup> HCA was granted a waiver from conducting an *in vivo* bioequivalence study and approved on June 26, 1995. The generic and pioneer products contain the same active and inactive ingredients and are soluble powders.

### **IV. HUMAN FOOD SAFETY:**

#### **A. TOLERANCES:**

Tolerances are established in 21 CFR 556.500 for the sum of residues in tissues of swine and turkeys as follows: 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney. The acceptable daily intake (ADI) for total oxytetracycline residues is 25 micrograms per kilogram of body weight per day.

#### **B. WITHDRAWAL TIME:**

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for pioneer oxytetracycline soluble powders (NADA 130-435, Alpharma, Inc.'s Oxytet Soluble<sup>®</sup>) is established under 21 CFR 520.1660d. Alpharma, Inc. received approval on November 29, 2000, for a zero day withdrawal time for turkeys and swine. This supplemental ANADA requests

the same zero-day withdrawal period for turkeys and swine based on the waiver granted to the original approval of Bimeda, Inc.'s ANADA. No new data were required for the reduced withdrawal times in swine and turkeys.

#### C. REGULATORY METHODS:

The regulatory method for determination of oxytetracycline in tissues is a microbiological assay procedure using *Bacillus cereus* var. *mycoides* (ATCC 11778) suspension and is found in the FDA publication "Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols" revised October 1968, reprinted December 1974.

#### V. AGENCY CONCLUSIONS

This supplemental ANADA satisfies the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and implementing regulations at Part 514 of Title 21, Code of Federal Regulations (21 CFR 514) which demonstrates that TETROXY® HCA (oxytetracycline HCl), is safe and effective for use in turkeys and swine for the approved indications, when administered in water at the approved dose.

Tolerances are established in 21 CFR 556.500 for the sum of residues in tissues of swine and turkeys as follows: 2 ppm in muscle, 6 ppm in liver, 12 ppm in fat and kidney. The preslaughter withdrawal times for turkeys and swine are zero days. The acceptable daily intake (ADI) for total oxytetracycline residues is 25 micrograms per kilogram of body weight per day.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals does not qualify for marketing exclusivity.

#### VI. APPROVED PRODUCT LABELING (attached)

- A. Pioneer Facsimile label – OXYTET Soluble (280 grams packet)
- B. Generic Facsimile labels – TETROXY HCA-280 g (9.87 oz), 560 g (19.74 oz)  
1400g (3.09 lbs) & 2270 g (5 lbs.)

# MIXING INSTRUCTIONS FOR WATER MEDICATION

CHICKENS - TURKEYS - SWINE

DOSAGE AND INDICATIONS FOR USE IN WATER PROPORTIONERS:

Add the following amount to one gallon of stock solution when proportioner is set to meter at the rate of one ounce per gallon.

	Disease	Treatment Level	Quantity/Gallon Stock Solution
CHICKENS	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline	200-400 mg	70-140 g
	Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline	400-800 mg	140-280 g
	Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline	400-800 mg	140-280 g
TURKEYS	Control of hexamitiasis caused by <i>Hexamita meleagridis</i> , susceptible to oxytetracycline	200-400 mg	70-140 g
	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline	400 mg	140 g
	GROWING TURKEYS: Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus enteritis), susceptible to oxytetracycline	25 mg/lb body weight	Varies with age & water consumption
SWINE	FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE: Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline. Bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.	10 mg/lb body weight	Varies with age & water consumption

**DIRECTIONS FOR USE:** Mix fresh solutions daily. Use as sole source of drinking water - Do not mix this product directly with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers. If improvement is not noted within 24 to 48 hours, consult a poultry veterinarian or poultry diagnostic laboratory - As a generalization, 200 chickens will drink one gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer 7 to 14 days to chickens & turkeys and up to 5 days to swine. Note: The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the birds, feed consumption rate, and the environmental temperature and humidity, each of which affects water consumption. CAUTION: Use as sole source of oxytetracycline. Not to be used for more than 14 consecutive days in chickens and turkeys or 5 consecutive days in swine.

**WARNING:** DO NOT feed to birds producing eggs for human consumption. Discontinue treatment of CHICKENS, TURKEYS and SWINE 0 days prior to slaughter. CONSULT MATERIAL SAFETY DATA SHEET PRIOR TO USE.

Tetroxy is a registered trademark of the Cross Vetpharm Group, Ltd DBA Bimeda, Inc.

RECOMMENDED STORAGE CONDITIONS: Store below 77°F (25°C).

LIVESTOCK REMEDY, NOT FOR HUMAN CONSUMPTION. HAZARDOUS REMEDY

Product No. 1TET011  
5TET001-501



# TETROXY® HCA-2270 SOLUBLE POWDER

## (OXYTETRACYCLINE HCl) ANTIBIOTIC

This 5 lb. (2.27 kg) container contains 830.2 g oxytetracycline HCl and will make:  
4151 gallons (15712 L) containing 200 mg oxytetracycline HCl per gallon.  
2075 gallons (7854 L) containing 400 mg oxytetracycline HCl per gallon.  
1038 gallons (3929 L) containing 800 mg oxytetracycline HCl per gallon.  
5 lbs. (2.27 kg) will treat 83,017 pounds of swine.

FOR USE IN DRINKING WATER ONLY  
NOT FOR USE IN LIQUID FEED SUPPLEMENTS  
SEE PANEL FOR INSTRUCTIONS  
KEEP OUT OF REACH OF CHILDREN

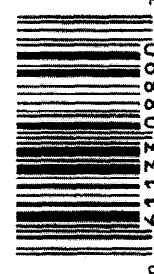
NET WEIGHT: 5 lbs. (2.27 kg)  
(2,270 grams)

ANADA 200-144, Approved by FDA



Bimeda

◆ Made in Canada



Manufactured For:  
Bimeda, Inc.  
Riverside, MO 64150 USA

# **TETROXY<sup>®</sup> HCA-560**

## **SOLUBLE POWDER**

### **(OXYTETRACYCLINE HCl) ANTIBIOTIC**

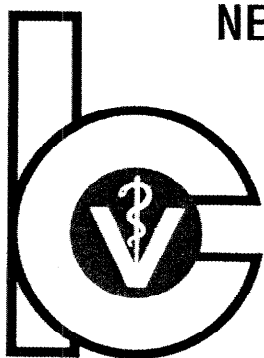
Each packet contains 204.8 g oxytetracycline HCl and will make:  
1024 gallons (3876 L) containing 200 mg oxytetracycline HCl per gallon.  
512 gallons (1938 L) containing 400 mg oxytetracycline HCl per gallon.  
256 gallons (969 L) containing 800 mg oxytetracycline HCl per gallon.  
This packet will treat 20,480 pounds of swine.

**FOR USE IN DRINKING WATER ONLY  
NOT FOR USE IN LIQUID FEED SUPPLEMENTS  
SEE BACK FOR INSTRUCTIONS**

**KEEP OUT OF REACH OF CHILDREN**

**NET WEIGHT: 19.74 oz. (560 Grams)**

**ANADA 200-144, Approved by FDA**



**Bimeda**

Manufactured for:  
**Bimeda, Inc.**  
Riverside, MO 64150 USA

## MIXING INSTRUCTIONS FOR WATER MEDICATION CHICKENS - TURKEYS - SWINE

**DOSAGE AND INDICATIONS FOR USE IN WATER PROPORTIONERS** - Add the following amount to one gallon of stock solution when proportioner is set to meter at the rate of one ounce per gallon.

	DISEASE	TREATMENT LEVEL	PACKS/GAL. STOCK SOL.
CHICKENS	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline	200-400 mg	1/4 - 1/2 (70-140 g)
	Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline.	400-800 mg	1/2 - 1 (140-280 g)
	Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	400-800 mg	1/2 - 1 (140-280 g)
TURKEYS	Control of hexamitiasis caused by <i>Hexamita meleagridis</i> , susceptible to oxytetracycline.	200-400 mg	1/4 - 1/2 (70-140 g)
	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	400 mg	1/2 (140 g)
	GROWING TURKEYS- Control of complicating bacteria organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline.	25 mg/lb. body weight	Varies with age & water consumption
SWINE	FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline. Bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	10 mg/lb. body weight	Varies with age & water consumption
	FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.		

### DIRECTIONS FOR USE

MIX FRESH SOLUTIONS DAILY. USE AS SOLE SOURCE OF DRINKING WATER - DO NOT MIX THIS PRODUCT DIRECTLY WITH MILK OR MILK REPLACERS. ADMINISTER ONE HOUR BEFORE OR TWO HOURS AFTER FEEDING MILK OR MILK REPLACERS. IF IMPROVEMENT IS NOT NOTED WITHIN 24 TO 48 HOURS, CONSULT A POULTRY VETERINARIAN OR POULTRY DIAGNOSTIC LABORATORY - AS A GENERALIZATION, 200 CHICKENS WILL DRINK ONE GALLON OF WATER PER DAY FOR EACH WEEK OF AGE. TURKEYS WILL CONSUME TWICE THAT AMOUNT. ADMINISTER 7 TO 14 DAYS TO CHICKENS & TURKEYS AND UP TO 5 DAYS TO SWINE. **NOTE:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the birds, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption.

**CAUTION:** USE AS SOLE SOURCE OF OXYTETRACYCLINE.

NOT TO BE USED FOR MORE THAN 14 CONSECUTIVE DAYS IN CHICKENS AND TURKEYS OR 5 CONSECUTIVE DAYS IN SWINE.



**WARNING:** DO NOT FEED TO BIRDS PRODUCING EGGS FOR HUMAN CONSUMPTION.  
DISCONTINUE TREATMENT OF CHICKENS, TURKEYS AND SWINE 0 DAYS PRIOR TO SLAUGHTER.  
CONSULT MATERIAL SAFETY DATA SHEET PRIOR TO USE.



Tetroxy is a registered trademark of the Cross Vetpharm Group, Ltd DBA Bimeda, Inc.

Product No. 1TET012  
8TET002-501

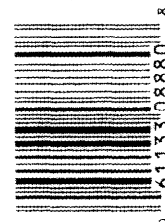
RECOMMENDED PACKET STORAGE CONDITIONS: Store below 77°F (25°C).  
LIVESTOCK REMEDY - NOT FOR HUMAN CONSUMPTION - HAZARDOUS REMEDY

TAKE TIME



♣ Made in Canada

654607B



## MIXING INSTRUCTIONS FOR WATER MEDICATION CHICKENS - TURKEYS - SWINE

**DOSAGE AND INDICATIONS FOR USE IN WATER PROPORTIONERS** - Add the following amount to one gallon of stock solution when proportioner is set to meter at the rate of one ounce per gallon.

	DISEASE	TREATMENT LEVEL	PACKS/GAL. STOCK SOL.
CHICKENS	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline	200-400 mg	1/8 - 1/4 (70-140 g)
	Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline.	400-800 mg	1/4 - 1/2 (140-280 g)
	Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	400-800 mg	1/4 - 1/2 (140-280 g)
TURKEYS	Control of hexamitiasis caused by <i>Hexamita meleagridis</i> , susceptible to oxytetracycline.	200-400 mg	1/8 - 1/4 (70-140 g)
	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	400 mg	1/4 (140 g)
	GROWING TURKEYS- Control of complicating bacteria organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline.	25 mg/lb. body weight	Varies with age & water consumption
SWINE	FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE		
	Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline.		
	Bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	10 mg/lb. body weight	Varies with age & water consumption
	FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.		

### DIRECTIONS FOR USE

MIX FRESH SOLUTIONS DAILY. USE AS SOLE SOURCE OF DRINKING WATER - DO NOT MIX THIS PRODUCT DIRECTLY WITH MILK OR MILK REPLACERS. ADMINISTER ONE HOUR BEFORE OR TWO HOURS AFTER FEEDING MILK OR MILK REPLACERS. IF IMPROVEMENT IS NOT NOTED WITHIN 24 TO 48 HOURS, CONSULT A POULTRY VETERINARIAN OR POULTRY DIAGNOSTIC LABORATORY - AS A GENERALIZATION, 200 CHICKENS WILL DRINK ONE GALLON OF WATER PER DAY FOR EACH WEEK OF AGE. TURKEYS WILL CONSUME TWICE THAT AMOUNT. ADMINISTER 7 TO 14 DAYS TO CHICKENS & TURKEYS AND UP TO 5 DAYS TO SWINE. **NOTE:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the birds, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption.

**CAUTION: USE AS SOLE SOURCE OF OXYTETRACYCLINE.**

NOT TO BE USED FOR MORE THAN 14 CONSECUTIVE DAYS IN CHICKENS AND TURKEYS OR 5 CONSECUTIVE DAYS IN SWINE.

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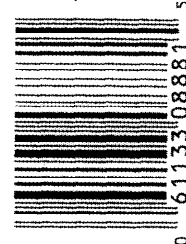
**WARNING:** DO NOT FEED TO BIRDS PRODUCING EGGS FOR HUMAN CONSUMPTION.  
DISCONTINUE TREATMENT OF CHICKENS, TURKEYS AND SWINE 0 DAYS PRIOR TO SLAUGHTER.  
CONSULT MATERIAL SAFETY DATA SHEET PRIOR TO USE.

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Tetroxy is a registered trademark of the Cross Vetpharm Group, Ltd DBA Bimeda, Inc.

RECOMMENDED PACKET STORAGE CONDITIONS: Store below 77°F (25°C).  
LIVESTOCK REMEDY - NOT FOR HUMAN CONSUMPTION - HAZARDOUS REMEDY

Product No. 1TET013  
8TET004-501



TAKE TIME



OBSERVE LABEL  
DIRECTIONS

🍁 Made in Canada

6546088



# **TETROXY® HCA-280**

## **SOLUBLE POWDER**

**(OXYTETRACYCLINE HCl)  
ANTIBIOTIC**

Each packet contains 102.4 grams of oxytetracycline HCl and will make:  
512 gallons (1938 L) containing 200 mg oxytetracycline HCl per gallon.  
128 gallons (484 L) containing 800 mg oxytetracycline HCl per gallon.

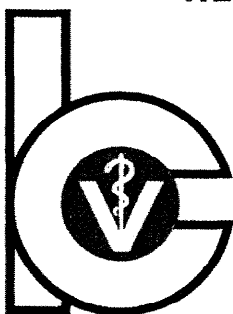
**FOR USE IN DRINKING WATER ONLY  
NOT FOR USE IN LIQUID FEED SUPPLEMENTS  
SEE BACK FOR INSTRUCTIONS**

**Restricted Drug (California) - Use Only as Directed**

**KEEP OUT OF REACH OF CHILDREN**

**NET WEIGHT: 9.87 oz. (280 Grams)**

**ANADA 200-144, Approved by FDA**



**Bimeda**

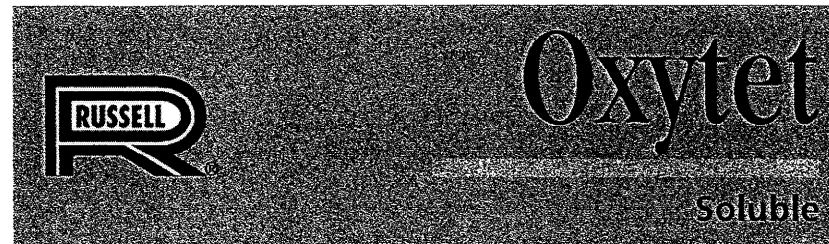
Manufactured for:  
**Bimeda, Inc.**  
Riverside, MO 64150 USA

**Dosage and indications for use in water proportioners** - Add the following amount to 1 gallon of stock solution when proportioner is set to meter at the rate of 1 oz per gallon.

C H I C K E N S	Disease	Treatment Level	Packs/Gallon Stock
	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	200 - 400 mg	1/4-1/2 (70-140 g)
	Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline.	400 - 800 mg	1/2-1 (140-280 g)
	Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	400 - 800 mg	1/2-1 (140-280 g)
T U R K E Y S	Control of hexamitiasis caused by <i>Hexamita meleagridis</i> , susceptible to oxytetracycline.	200 - 400 mg	1/4-1/2 (70-140 g)
	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	400 mg	1/2 (140 g)
	GROWING TURKEYS - Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus enteritis), susceptible to oxytetracycline.	25 mg/lb body weight	Varies with age & water consumption
S W I N E	FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE - Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline.		
	Bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline. FOR BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.	10 mg/lb body weight	Varies with age & water consumption

Take Time  
Observe Label  
Directions

List #2201



## OXYTETRACYCLINE HCl ANTIBIOTIC

This packet contains 102.4 g of oxytetracycline HCl and will make:  
512 gallons (1936 liters) containing 200 mg oxytetracycline HCl per gallon  
128 gallons (484 liters) containing 800 mg oxytetracycline HCl per gallon

This packet will treat 10,240 lbs of swine

### RECOMMENDED PACKET STORAGE CONDITIONS:

Store below 77° F (25° C)

See back panel for instructions

NADA #130-435, Approved by FDA

For Use in Drinking Water Only  
Not for Use in Liquid Type B Medicated Feeds  
Keep Out of Reach of Children

Net Weight  
9.87 oz (280 g)

Restricted Drug, Use Only as Directed (CA)



Alpharma Inc.  
One Executive Drive, Fort Lee, New Jersey 07024

FDA AIF-031A 0007

**DIRECTIONS FOR USE:** Mix fresh solutions daily. Use as sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Consult a poultry diagnostic laboratory or poultry pathologist for diagnosis and advice on dosage for chickens and turkeys. As a generalization, 200 chickens will drink 1 gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer up to 5 days to swine and 7 to 14 days for chickens and turkeys. **NOTE:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption. **CAUTION:** Use as sole source of oxytetracycline. Not to be used for more than 5 consecutive days in swine or 14 consecutive days in chickens and turkeys.

**WARNING - Do not feed to birds producing eggs for human consumption. LIVESTOCK REMEDY. NOT FOR HUMAN USE. HAZARDOUS REMEDY.**



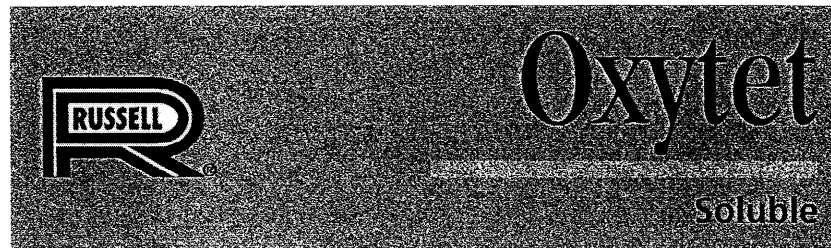
RUU LINES

**Dosage and indications for use in water proportioners** - Add the following amount to 1 gallon of stock solution when proportioner is set to meter at the rate of 1 oz per gallon.

	Disease	Treatment Level	Packs/Gallon Stock
C H I C K E N S	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	200 - 400 mg	1/4-1/2 (70-140 g)
	Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline.	400 - 800 mg	1/2-1 (140-280 g)
	Control of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline.	400 - 800 mg	1/2-1 (140-280 g)
I N D U C E D	Control of hexamiasis caused by <i>Hexamita meleagridis</i> , susceptible to oxytetracycline.	200 - 400 mg	1/4-1/2 (70-140 g)
	Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , susceptible to oxytetracycline.	400 mg	1/2 (140 g)
	GROWING TURKEYS - Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronavirus enteritis), susceptible to oxytetracycline.	25 mg/lb body weight	Varies with age & water consumption
S W I N E	FOR THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE - Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline. Bacterial pneumonia caused by <i>Pasteurella multocida</i> , susceptible to oxytetracycline. FOR BREEDING SWINE - Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.	10 mg/lb body weight	Varies with age & water consumption



List #2201



## OXYTETRACYCLINE HCl ANTIBIOTIC

This packet contains 102.4 g of oxytetracycline HCl and will make:  
512 gallons (1936 liters) containing 200 mg oxytetracycline HCl per gallon  
128 gallons (484 liters) containing 800 mg oxytetracycline HCl per gallon

This packet will treat 10,240 lbs of swine

### RECOMMENDED PACKET STORAGE CONDITIONS:

Store below 77° F (25° C)

See back panel for instructions

NADA #130-435, Approved by FDA

For Use in Drinking Water Only  
Not for Use in Liquid Type B Medicated Feeds  
Keep Out of Reach of Children

Net Weight  
9.87 oz (280 g)

Restricted Drug, Use Only as Directed (CA)



Alpharma Inc.  
One Executive Drive, Fort Lee, New Jersey 07024

FDA AHF-031A 0007

**DIRECTIONS FOR USE:** Mix fresh solutions daily. Use as sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Consult a poultry diagnostic laboratory or poultry pathologist for diagnosis and advice on dosage for chickens and turkeys. As a generalization, 200 chickens will drink 1 gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer up to 5 days to swine and 7 to 14 days for chickens and turkeys. **NOTE:** The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption. **CAUTION:** Use as sole source of oxytetracycline. Not to be used for more than 5 consecutive days in swine or 14 consecutive days in chickens and turkeys.

**WARNING - Do not feed to birds producing eggs for human consumption. LIVESTOCK REMEDY. NOT FOR HUMAN USE. HAZARDOUS REMEDY.**



<p><b>DIRECTIONS FOR USE:</b> Mix fresh solutions daily. Use as sole source of drinking water. Do not mix this product directly with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers. If improvement is not noted within 24 to 48 hours, consult a poultry veterinarian or poultry diagnostic laboratory - As a generalization, 200 chickens will drink one gallon of water per day for each week of age. Turkeys will consume twice that amount. Administer 7 to 14 days for chickens and turkeys and up to 5 days to swine.</p> <p><b>Note:</b> The concentration of drug required in medicated water must be adequate to compensate for variation in the age of the animal, feed consumption rate, and the environmental temperatures and humidity, each of which affects water consumption.</p> <p><b>CAUTION:</b> USE AS SOLE SOURCE OF OXYTETRACYCLINE. NOT TO BE USED FOR MORE THAN 14 CONSECUTIVE DAYS IN CHICKENS AND TURKEYS OR 5 CONSECUTIVE DAYS IN SWINE.</p> <p>⇒ <b>WARNING:</b> DO NOT FEED TO BIRDS PRODUCING EGGS FOR HUMAN CONSUMPTION. DISCONTINUE TREATMENT OF CHICKENS, TURKEYS AND SWINE 0 DAYS PRIOR TO SLAUGHTER. CONSULT MATERIAL SAFETY DATA SHEET PRIOR TO USE.</p> <p><b>RECOMMENDED PACKET STORAGE CONDITIONS:</b> Store below 77°F (25°C)</p> <p>Tetroxy is a registered trademark of the Cross Vetpharm Group, Ltd DBA Bimeda, Inc. Lot No. Exp</p>	<p style="text-align: center;"><b>TETROXY HCA-1400 SOLUBLE POWDER (OXYTETRACYCLINE HCl) ANTIBIOTIC</b></p> <p>Each bottle contains 512 grams of Oxytetracycline HCl and will make: 2560 gallons (9690L) containing 200mg oxytetracycline HCl per gallon 1280 gallons (4845L) containing 400mg oxytetracycline HCl per gallon 640 gallons (2422L) containing 800mg oxytetracycline HCl per gallon This bottle will treat 51,200 pounds of swine.</p> <p style="text-align: center;">FOR USE IN DRINKING WATER ONLY NOT FOR USE IN LIQUID FEED SUPPLEMENTS</p> <p style="text-align: center;">LIVESTOCK REMEDY - NOT FOR HUMAN CONSUMPTION - HAZARDOUS REMEDY KEEP OUT OF REACH OF CHILDREN</p> <p style="text-align: center;">Restricted Drug (California) - Use Only as Directed</p> <p style="text-align: center;">NET WEIGHT: 3.09 LBS. (1400 GRAMS)</p> <p style="text-align: center;">ANADA 200-144, Approved by FDA</p> <p>Bimeda</p> <p style="text-align: right;">Manufactured by: Bimeda, Inc. Le Sueur, MN 56058</p>	<p style="text-align: center;"><b>MIXING DIRECTIONS FOR WATER MEDICATION CHICKENS - TURKEYS - SWINE</b></p> <p><b>DOSAGE AND INDICATIONS FOR USE IN WATER PROPORTIONERS</b> - Add 1 bottle to the following amount of water to make a stock solution for use in a proportioner set to meter at the rate of one ounce per gallon.</p> <table border="1"> <thead> <tr> <th>Disease</th><th>Treatment Level</th><th>Gallons Stock/Bottle</th></tr> </thead> <tbody> <tr> <td>C Control of infectious synovitis caused by <i>Mycoplasma synoviae</i>, H susceptible to oxytetracycline.</td><td>200 - 400 mg</td><td>20 - 10</td></tr> <tr> <td>I Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i>, susceptible to oxytetracycline.</td><td>400 - 800 mg</td><td>10 - 5</td></tr> <tr> <td>E Control of fowl cholera caused by <i>Pasteurella multocida</i>, N susceptible to oxytetracycline.</td><td>400 - 800 mg</td><td>10 - 5</td></tr> <tr> <td>S</td><td></td><td></td></tr> <tr> <td>T Control of hexamitiasis caused by <i>Hexamita meleagridis</i>, U susceptible to oxytetracycline.</td><td>200 - 400 mg</td><td>20 - 10</td></tr> <tr> <td>R Control of infectious synovitis caused by <i>Mycoplasma synoviae</i>, K susceptible to oxytetracycline.</td><td>400 mg</td><td>10</td></tr> <tr> <td>E GROWING TURKEYS-Control of complicating bacteria Y associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline.</td><td>25 mg/lb. body weight</td><td>Varies with age &amp; water consumption</td></tr> <tr> <td>S</td><td></td><td></td></tr> <tr> <td>W Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i>, susceptible to oxytetracycline.</td><td>10 mg/lb. body weight</td><td>Varies with age &amp; water consumption</td></tr> <tr> <td>N Bacterial pneumonia caused by <i>Pasteurella multocida</i>, E susceptible to oxytetracycline.</td><td></td><td></td></tr> </tbody> </table> <p><b>FOR BREEDING SWINE:</b> Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by <i>Leptospira pomona</i>, susceptible to oxytetracycline.</p>	Disease	Treatment Level	Gallons Stock/Bottle	C Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , H susceptible to oxytetracycline.	200 - 400 mg	20 - 10	I Control of chronic respiratory disease (CRD) and air sac infections caused by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , susceptible to oxytetracycline.	400 - 800 mg	10 - 5	E Control of fowl cholera caused by <i>Pasteurella multocida</i> , N susceptible to oxytetracycline.	400 - 800 mg	10 - 5	S			T Control of hexamitiasis caused by <i>Hexamita meleagridis</i> , U susceptible to oxytetracycline.	200 - 400 mg	20 - 10	R Control of infectious synovitis caused by <i>Mycoplasma synoviae</i> , K susceptible to oxytetracycline.	400 mg	10	E GROWING TURKEYS-Control of complicating bacteria Y associated with bluecomb (transmissible enteritis, coronaviral enteritis), susceptible to oxytetracycline.	25 mg/lb. body weight	Varies with age & water consumption	S			W Bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> , susceptible to oxytetracycline.	10 mg/lb. body weight	Varies with age & water consumption	N Bacterial pneumonia caused by <i>Pasteurella multocida</i> , E susceptible to oxytetracycline.		
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3.09 lbs / 1400 grams

# MIXING INSTRUCTIONS FOR WATER MEDICATION

CHICKENS - TURKEYS - SWINE

DOSAGE AND INDICATIONS FOR USE IN WATER PROPORTIONERS:

Add the following amount to one gallon of stock solution when proportioner is set to meter at the rate of one ounce per gallon.

Disease	Treatment Level	Quantity/Gallon Stock Solution
rot of infectious synovitis caused by <i>Mycoplasma synoviae</i> , aptible to oxytetracycline	200-400 mg	70-140 g
rot of chronic respiratory disease (CRD) and air sac infections ed by <i>Mycoplasma gallisepticum</i> and <i>Escherichia coli</i> , aptible to oxytetracycline.	400-800 mg	140-280 g
rot of fowl cholera caused by <i>Pasteurella multocida</i> , susceptible yltetracycline.	400-800 mg	140-280 g
rot of hexamitiasis caused by <i>Hexamita meleagridis</i> , susceptible yltetracycline.	200-400 mg	70-140 g
rot of infectious synovitis caused by <i>Mycoplasma synoviae</i> , aptible to oxytetracycline.	400 mg	140 g
WING TURKEYS: Control of complicating bacterial organisms associated with omba (transmissible enteritis, coronavirus enteritis), susceptible to oxytetracycline.	25 mg/lb body weight	Varies with age & water consumption
THE CONTROL AND TREATMENT OF THE FOLLOWING DISEASES IN SWINE: Bacterial enteritis caused by <i>Escherichia coli</i> and onella choleraesuis, susceptible to oxytetracycline. Bacterial pneumonia ed by <i>Pasteurella multocida</i> , susceptible to oxytetracycline. BREEDING SWINE: Leptospirosis (reducing the incidence of abortions and iding of leptospires) caused by <i>Leptospira pomona</i> , susceptible to oxytetracycline.	10 mg/lb body weight	Varies with age & water consumption

NS FOR USE: Mix fresh solutions daily. Use as sole source of drinking water - Do not mix this product directly with milk or milk. Administer one hour before or two hours after feeding milk or milk replacers. If improvement is not noted within 24 to 48 hours, oultry veterinarian or poultry diagnostic laboratory - As a generalization, 200 chickens will drink one gallon of water per day for of age. Turkeys will consume twice that amount. Administer 7 to 14 days to chickens & turkeys and up to 5 days to swine. concentration of drug required in medicated water must be adequate to compensate for variation in the age of the d consumption rate, and the environmental temperature and humidity, each of which affects water consumption.  
Use as sole source of oxytetracycline. Not to be used for more than 14 consecutive days in chickens and turkeys or 5 ve days in swine.

WING: DO NOT feed to birds producing eggs for human consumption. Discontinue treatment of CHICKENS, TURKEYS and SWINE 0 days prior to slaughter. CONSULT MATERIAL SAFETY DATA SHEET PRIOR TO USE.

a registered trademark of the Cross Vetpharm Group, Ltd DBA Bimeda, Inc.  
ENDED STORAGE CONDITIONS: Store below 77°F (25°C).

CK REMEDY, NOT FOR HUMAN CONSUMPTION. HAZARDOUS REMEDY

Product No. 1TET011  
8TET001-501



# TETROXY® HCA-2270 SOLUBLE POWDER (OXYTETRACYCLINE HCl) ANTIBIOTIC

This 5 lb. (2.27 kg) container contains 830.2 g oxytetracycline HCl and will make:  
4151 gallons (15712 L) containing 200 mg oxytetracycline HCl per gallon.  
2075 gallons (7854 L) containing 400 mg oxytetracycline HCl per gallon.  
1038 gallons (3929 L) containing 800 mg oxytetracycline HCl per gallon.  
5 lbs. (2.27 kg) will treat 83,017 pounds of swine.

FOR USE IN DRINKING WATER ONLY  
NOT FOR USE IN LIQUID FEED SUPPLEMENTS  
SEE PANEL FOR INSTRUCTIONS  
KEEP OUT OF REACH OF CHILDREN

NET WEIGHT: 5 lbs. (2.27 kg)  
(2,270 grams)

ANADA 200-144, Approved by FDA



Bimeda

◆ Made in Canada

Manufactured For:  
Bimeda, Inc.  
Riverside, MO 64150 USA



EXP.  
LOT